

REMARKS

It is requested that the Amendment dated January 13, 2009 be entered and re-considered. The claims are those of the un-entered Amendment; no claims have been amended or added in this reply.

The Notice of Non-Compliant Amendment states that claim 34 was not previously present. This is error on the Examiner's part. First, claim 34 appears at the top of page 6 of the Amendment dated April 29, 2008. Further, on page 2, first paragraph of the Office Action dated August 19, 2008 the Examiner states that claim 34 has been added and is pending. On page 3 of the same Action claim 34 is both objected to and rejected. Therefore, the statement that the Amendment of January 13, 2009 is "non-compliant" because claim 34 was not previously present is in error and the issuance of the Notice is improper. Correction is requested.

The refusal to enter the Amendment of January 13, 2009 is also deemed to be improper. The Amendment: 1) raised no new issues; 2) did not present additional claims without cancellation of a corresponding number of finally rejected claims; 3) did place the case in condition for allowance; and 4) did reduce the number of issues on appeal.

In the Advisory Action, the Examiner relies on claim 32 and new claims 35-36 as the basis for refusal to enter the Amendment. Claim 32 was rejected in the Action dated August 19, 2008 solely under 35 USC 112 and objected to for failure to end in a period. In the Amendment, a period was added and the amount of diclofenac was amended to recite 0.1% instead of 0.01%. The recitation of 0.01% was clearly a typographical error, especially in view of applicant's statement on page 8 of the Amendment dated April 29, 2008 that 0.1% is the minimal effective concentration. (Support for the 0.1% limitation was pointed out by the Examiner on page 4 of the Action dated August 13, 2008.) These changes mooted all bases for rejection under 35 USC 112 and also mooted the objection. No additional consideration or search would be needed as a result of these changes, *contra* to the Examiner's statement that these would be required. Similarly, the Examiner states in the Advisory Action that claims 35 and 36 would require a further search. However, as with claim 32, now-canceled claims 33 and 34 (which were redrafted as claims 35 and 36) were rejected solely under 35 USC 112 for the same reasons as claim 32. Claims 35 and 36 mooted these bases for rejection (as discussed *supra* for claim 32) and added some punctuation marks. Again, no further consideration or search is deemed to be required by these changes; and the Examiner has provided no explanation on what basis these would be required. It is therefore

submitted that reasons 3(a) and 3(d) provided in the Advisory Action are improper and it is requested that they be withdrawn.

Lastly, the Examiner has provided a rationale for not allowing the claims to pass to issue: the rejection of some claims under 35 USC 103 over Asche for the reasons previously provided in the Action dated August 19, 2008. The Examiner expands these reasons by stating that the teaching of the prior art (i.e., solely Asche) is not limited to its specific examples; i.e., that the Examiner can rely on the broad teaching of Asche and then cites the case of *In re Susi*, 169 USPQ 423, in support. Applicant traverses.

The Examiner's citation of *Susi* is in the form of a *per se* rule, i.e., that a broad teaching in the art inherently supports the obviousness rejection of a claim to a narrower invention. However, there is no such *per se* rule. If the Examiner wishes to rely on Asche, she must additionally point out with specificity how this teaching makes the present invention obvious. Here, the Examiner's attention is directed to MPEP 2144.08, wherein the topic of a case of *prima facie* obviousness based on a reference is discussed at length. The MPEP points out that merely because the claimed subject matter is encompassed by the art is not sufficient to establish a case of *prima facie* obviousness. Rather, the Examiner must consider the factors set out in *Graham v. Deere*. The Examiner must find motivation or suggestion in the teaching to one of ordinary skill in the art to make the claimed invention.

The MPEP recites criteria which the Examiner should adhere to in making a case for *prima facie* obviousness. These include, but not limited to: 1) identifying the motivation found in the art to make the invention; 2) evaluating the art from the standpoint of one of ordinary skill in the art; 3) determining whether one of ordinary skill would be motivated to make the invention (i.e., to actually select the claimed subject matter from the art's genus; 4) considering the preferred species taught in the art; 5) considering the number of variables which must be selected from the art to make the invention; and 6) specifically articulating what teaching or suggestions in the art would have motivated one of ordinary skill to select the claimed species or subgenera. Finally, MPEP 2144.08 states that conclusory statements without articulated rationale or evidentiary support do not constitute sufficient factual findings. Without these, it is deemed that there is no basis for the Examiner's rejection based on obviousness.

Additionally, the Examiner has ignored the narrowing language of claims 17-19, 31-32, and 35-36. Nowhere does Asche teach or suggest compositions of such narrow scope.

It is submitted that the Examiner has not met the burden of proof necessary for a rejection under 35 USC 103. On the other hand, applicants have provided ample reasons why Asche does not make obvious the claimed invention (see page 2 of the Amendment dated January 13, 2009).

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These reasons have been dismissed by the Examiner by improperly citing *In re Susi* in a *per se* manner, as discussed *supra*.

It is again requested that the un-entered amendment be entered. The Examiner is further requested to reconsider all bases for rejection, objection, and claim interpretation in view of the amendments and all the remarks and to pass the case to issue.

Respectfully submitted,



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